Department of Public Health
Board of Registration in Pharmacy
Division of Medical Assistance

Medication Management Task Force

Report to the
Joint Committee on Health Care
House Committee on Ways and Means
Senate Committee on Ways and Means

Recommendations on Improving Medication Management to Reduce Medication Waste in the Commonwealth

June 2003

Table of Contents

Introduction

Massachusetts is experiencing both an increase in pharmacy expenditures and a decrease in resources to cover these expenditures. Implementation of measures to better manage medications, including controlling and limiting medication waste, is an important priority. Medication waste can include the actual physical destruction and disposal of unused pharmaceuticals. Medication waste also occurs when a drug therapy is ineffective and does not benefit the patient. This may be due to the prescribing and consumption of medications that are therapeutically inappropriate or unnecessary, or prescribed at sub-therapeutic doses or for inadequate periods of time.

On August 14, 2002, the Massachusetts Legislature passed into law, Chapter 282 of the Acts of 2002 (Attachment 1), An Act Reducing Medication Waste in Certain Licensed Facilities. Pursuant to the Act, the Department of Public Health (DPH), in conjunction with the Board of Registration in Pharmacy (BRP) and the Division of Medical Assistance (DMA), convened the Medication Management Task Force to review and recommend methods to reduce medication waste in facilities licensed by the DPH, Department of Mental Health (DMH) and the Department of Corrections (DOC). These include Long Term Care Facilities (LTCFs) , certain licensed residential facilities and correctional institutions, herein referred to as "residential and correctional facilities." The Task Force determined that methods must be practical, flexible and economical for integration into the drug therapy for today's patients

The challenge of medication management in the facilities mentioned in the legislation depends on the type of patient or resident. In general, LTCF residents today are no longer individuals who have lost the capacity for self-care due to chronic illness and advanced age but are individuals with temporary needs for skilled nursing care because their capacity for self-care is on hold due to trauma or illness. The State Office of Pharmacy Services (SOPS) provides pharmaceutical care for patients in the care of DMH and the Department of Mental Retardation (DMR), in state hospitals, and inmates within correctional facilities, populations that are more stable than those at LTCFs. Accordingly, in these different settings, approaches to medication management may be similar; however, individual methods recommended by the Task Force may not be applicable across all of the settings.

Agency Collaboration

Prior to enactment of Chapter 282 of the Acts of 2002, DPH, BRP and DMA had begun to discuss medication management issues of common concern. The agencies began meeting in the fall of 2001 and focused first on the return of unused medications for redispensing. Based on results of a pilot project conducted in the mid 1990s, DPH and BRP had determined that unit-dose packaged and certain unsealed multi-dose packages could be allowed to be returned for redispensing. In spring, 2002, DPH issued guidelines and policies that allowed for the return of certain medications in unit-dose packaging from LTCFs. Concurrently, BRP issued a policy for pharmacists regarding the safe redispensing of medications returned from LTCFs. With these policies and guidelines in place, DMA proceeded to promulgate and implement regulations for the mandatory return of eight of the costliest drugs (based on volume) dispensed to residents in LTCFs. To facilitate the implementation of this regulation, DMA produced best practices for LTCFs and pharmacies, a training curriculum for LTCFs, and a start-up implementation support center. All of the agencies' activities involved collaborating with industry and other interested parties prior to the implementation of policies and regulations.

Process

Gathering information from the literature, other states, local experts and stakeholders.

The Task Force conducted two surveys. The BRP surveyed states on the use of automated pharmacy systems. (Attachment 2) The DPH and the DMA surveyed equivalent public health and Medicaid assistance programs in other states to gather data on reimbursements and methods used to reduce medication waste. (Attachments 3 and 4) A trade publication was also referenced for comparison of states. (Attachment 5)

A stakeholder conference was held on October 28, 2002. Invitees were representatives of the agencies and professional organizations listed in section (b) of Chapter 282 and other stakeholders. (Attachment 6) Three topic areas -- technology, standards and economics -- were chosen as foci for the conference to elicit as much input from attendees as possible regarding the issues put forth by the legislature. During the program, the group identified methods to reduce medication waste.

Presentation of recommended methods.

Below is a chart of the Task Force's recommended methods to reduce medication waste. The Task Force did not rate or rank the methods because no data quantifying the reduction in waste on which to base such an assessment was found in the literature or the surveys. It was beyond the scope of the Task Force to examine potential costs to implement these methods.

One additional recommendation made by the conferees, with which the agencies concur, is to plan for demonstration projects of adopted methods. The legislature intended that recommended methods not negatively affect other areas of the health care delivery system. Demonstration projects to study recommended methods would provide the data needed to answer this charge.

Chart of Methods Recommended To Reduce Medication Waste

Method	**Regulatory/Statutory Changes Required**	**Status**	**Require Involvement of Agencies Outside of the Task Force**
Use of Medical Practice Guidelines	None	Being done now on a limited basis (DMA reviews records for poly-pharmacy)	None
Prescription Ordering (Initial and Refills)	None	Being done now on a limited basis	None
Academic or Counter Detailing	None	Being done now in DOC; DMA is beginning program	None
Collaborative Practice	Yes (S. 630 and S. 573)	Not allowed at present	Board of Registration in Medicine
Formularies/Drug Lists	None	Used by State Office of Pharmacy Services; DMA utilizes the MassHealth Drug List	None
Therapeutic Interchange	None	Some application in restricted settings	US Drug Enforcement Administration
Prior Authorization	None	Being done now by DMA	None
Automated Pharmacy System	None	Not being done	U.S. Drug Enforcement Administration
Return for Redispensing	None	Being done now	None
Release Medication With Patient Upon Discharge	None	Being done now	None

BACKGROUND

Agencies' Missions Regarding Reduction of Medication Waste

The Department of Public Health, through its Drug Control Program, ensures access to safe and effective pharmaceutical care and protects consumers against unsafe practices in the handling and distribution of pharmaceuticals. The Department has statutory responsibility to set standards for the distribution of pharmaceuticals by health care facilities and community programs.

The Board of Registration in Pharmacy in the Department of Public Health establishes standards for and oversees the provision of quality pharmaceutical care through regulation of the practice of pharmacy and the distribution of prescription drugs and devices.

The Division of Medical Assistance strives to ensure the utilization of safe and cost-effective drugs, reduce waste and purchase pharmaceuticals at the lowest price possible.

Task Force Project Leaders

Task Force project leaders are for DPH, Adèle Audet; BRP, Charles Young and DMA, Rita Sevier. Tim MacIntyre, represents DPH, Division of Health Care Quality.

Addressing Medication Management Prior to Chapter 282

Special Project: Dispensing of Unit Dose Medications in LTCFs

In 1996, DPH presented a special report on the dispensing of unit dose medications in LTCFs to the Joint Committee on Health Care. This report showed that the use of unit-dose packaging as a method for medication distribution and administration in LTCFs as well as return for redispensing could be a safe and effective means to reduce medication waste.

DMA, BRP and DPH Collaboration for Return for Redispensing in LTCFs

In fall 2001, DPH, BRP and DMA, lead by DMA's Unit Dose/Return for Redispensing Project, began to discuss medication waste and how methods of medication management could address the issue. The term "medication management" includes, but is not limited to, the following activities: ordering, dispensing, administering, labeling, security, storage and disposal of drugs, counseling, drug utilization review, stop orders, and emergency and non-routine dispensing procedures. According to M.G.L. 111 §25I (Attachment 7), certain medications dispensed to individual patients may be returned for credit to the pharmacy from which the medication was dispensed. In winter 2001-2002, the agencies held meetings with stakeholder groups to discuss proposed regulations, guidelines and policies for implementing M.G.L. c. 111 §25I and allowing the return of prescription drugs dispensed to residents of LTCFs.

In April 2002, the DPH and BRP finalized their policy documents for implementing M.G.L. c. 111 §25I. DPH issued "Guidelines for Use of Unit-Dose Packaging for the Management and Administration of Pharmaceuticals in Long Term Care Facilities" and the "Policy on Return for Redispensing of Medications from Long Term Care Facilities". (Attachments 8 and 9) These established the standards under which LTCFs could return certain unused Schedule VI unit-dose packaged and over-the counter medications to pharmacies. The BRP issued Policy PH 2002 - 01, "Policy on Return for Redispensing of Medication from Long Term Care Facilities." (Attachment 10) This policy allowed pharmacies to accept medications, dispensed to individual patients in LTCFs, for return. Simultaneously, members of DMA's Unit-Dose Return and Redispense Project met with stakeholders to discuss proposed regulations that would require LTCFs to return eight of the most costly drugs (Depakote, Neurontin, Paxil, Prevacid, Remeron, Risperdal, Zoloft and Zyprexa, based on volume) representing 34 total drug products/dosage forms. The list of drugs can be modified quickly by DMA, as necessary. Promulgation and implementation of DMA's regulations in June 2002 (Transmittal Letters NF-43 and PHM-45, Attachments 11 and 12) included regulations and best practices for LTCFs and pharmacies, a training curriculum for LTCFs and start-up implementation support. An advisory group continues to meet with DMA representatives to address areas of managing waste, pharmacy costs and quality of care issues in nursing facilities.

DOC Return for Redispensing of Medications Dispensed to Inmates

In July 2001 the DOC and the State Office of Pharmacy Services (SOPS) contracted with a vendor, McKesson, for equipment and software programs to repackage selected bulk solid oral dosage forms into unit-dose containers. The SOPS determines which drugs will be returned for redispensing based on cost impact and waste data. (Attachment 13) Adding or deleting drugs from this list is easier than the adding or deleting from the DMA list since this is a closed system and the list is not in regulation. This facilitates a quicker response to changes in population, prescribing practice or drug cost and availability. The Director of the State Office of Pharmacy Services says that return for redispensing to date has produced saving of approximately $300,000 per year. The initial expense for equipment and software was $65,000.

REPORT

Introduction

Massachusetts is experiencing both an increase in pharmacy expenditures and a decrease in resources to cover these expenditures. Implementation of measures to control and limit medication waste is an important priority. Medication waste can include the actual physical destruction and disposal of pharmaceuticals, medications that are therapeutically inappropriate or unnecessary and do not benefit the patient, and medications that are prescribed at sub-therapeutic doses or for inadequate periods of time.

On August 14, 2002, Chapter 282 of the Acts of 2002, An Act Reducing Medication Waste in Certain Licensed Facilities, was enacted. Pursuant to Act, the Department of Public Health (DPH), in conjunction with the Board of Registration in Pharmacy (BRP) and the Division of Medical Assistance (DMA) convened the Medication Management Task Force to review and recommend methods to reduce medication waste in facilities licensed by the DPH, Department of Mental Health (DMH) and the Department of Corrections (DOC).

The Task Force determined that methods to reduce waste should not impose unreasonable costs on the health care delivery system, patient outcomes should be maintained or improved, and solutions should be found that are practical, flexible and economical for integration into the drug therapy of patients.

Resources for consultation were listed in Chapter 282 Section 1 (b). The Act stated that the Task Force shall consult the Boards of Registration in Medicine and Nursing, the Department of Mental Health and the Department of Corrections. In addition, the lead agencies could approach other resources for consultation beyond the expertise of Task Force members or listed consultants.

Process

The Task Force's first meeting was held on September 11, 2002. The Task Force established a group understanding of the statutory language (current technology, standards and reimbursement mechanisms for dispensing and distribution medications to facilities, other states' requirements for limiting prescription drug waste and any cost savings realized; the commonwealth's standards for return and re-dispensing of patient specific schedule VI prescription drugs and possible incentive mechanisms to prevent the creation of prescription drug waste) and the meaning of "without imposing unreasonable costs on the health care delivery system." Assessing the financial impact of any changes in pharmaceutical care (the field of pharmacoeconomics) would require consultation with an expert in that area of study. The Task Force recognized that any discussions of reimbursement or incentive mechanisms were outside the jurisdiction of the Task Force.

Literature searches were performed, and Task Force members and staff at the three lead agencies contacted other states. The Task Force conducted two surveys of other states: the BRP obtained information from 28 states on the use of automated dispensing machines in LTCFs and whether pharmacies or pharmacy departments were allowed to exist within LTCFs; and the DPH and DMA surveyed other states' public health and Medicaid assistance programs and Boards of Pharmacy. (see attachments 2, 3 and 4 for survey questions and results)

A stakeholder conference was held on October 28, 2002. The Task Force engaged Richard Gleason, a conference facilitator and adult educator from the Division of Professional Licensure, who assisted in the general planning of the meeting and the format for the invited experts and the small workgroup exercises. Three topic areas were chosen as foci for the conference; technology, standards, and economics. Stephen Feldman, President of the American Society of Consultant Pharmacists spoke about pharmacy technology, Robert Paone, member of the Board of Registration in Pharmacy presented on regulations, laws and protocols, and Judith Barr, Associate Professor of Pharmacy and Director of the National Education and Research Center for Outcomes Assessment at Northeastern University, discussed economics and evaluations. (see participant list, Attachment 6).

Facility Overview

Long Term Care Facilities

In general, medication waste is the result of out-of-date or sub-optimal drug therapies, inefficient medication ordering procedures, poor discharge planning and other factors. According to the 1999 National Nursing Home Survey, 94.1% of all residents received "prescribed and non-prescribed" medicines in the immediate 30 days prior

to record review[1]. High utilization of prescription medications underscores the need to adopt safe and effective measures to address medication waste.

Medication waste is also the result of non-response to changes in the patient populations to more acute patients and the higher patient turnover seen in Massachusetts LTCFs today[2]. In the United States the percentage of nursing home discharges for residents whose length of stay was 3 months or less was 68.3%. In addition to being discharged to a residence, other events that can be anticipated during drug therapy could include discharge for admittance to hospital with return to LTCF, discontinuation of an antibiotic, increase or decrease of medication dosage depending on patient response and discontinuance of a medication that is causing side effects and loss of life.

A study published in 1996 examined the reasons for medication destruction and calculated that the cost of medication waste was $0.15 per patient day and the percentage of drug waste was 6.7% of the cost of medications dispensed in Massachusetts LTCFs[3]. According to DMA the total dollars in LTCFs in FY 2002 was $116,238,674.00 for medications in LTCFs.

Only by using a combination of improvements in existing functions and introduction of new practices can medication waste, caused by multiple factors be addressed. In general, the LTCF resident is no longer an individual who has lost the capacity for self-care due to chronic illness treated with simple medication regimens but is more typically an individual, with an acute illness treated with a complex medication regimen, with temporary needs for skilled nursing care. The reduction of medication waste in LTCFs will come from implementing practical technological and medical solutions that integrate the hundreds of new therapies in a population of the elderly whose capacity for self-care is not gone but on hold due to trauma or illness and a population of short term stay patients.

Department of Corrections and Departments of Mental Health and Mental Retardation

For purposes of this report, selected segments of the Departments of Corrections, Mental Health and Mental Retardation are considered "closed systems" because all aspects of pharmaceutical care are controlled by the State Office of Pharmacy Services either directly or through contracts. Closed systems have a measure of autonomy that is not experienced by pharmacies or LTCFs caring for residents in the community. Within closed, not-for-profit systems the challenges of medication management are much less complex than in open, for-profit systems.

Sites included in these systems are certain correctional facilities (certain MA Correctional Institution sites, houses of correction and county jails) and state hospitals. Within the DOC there are approximately 5100 inmates receiving medication. The population is relatively stable with respect to residency and disease state.

Clients of DMH and DMR in certain group homes and other independent living arrangements are considered to be living in private residences and disposal of their medications are not subject to medication return policies.

Limitations of Review and Recommendations

There is limited documentation of actual waste in LTCFs that can be used to determine the extent of the problem or to establish a baseline to measure a reduction in waste. Current and valid data are not available to compare medication waste from past practices with the changes after implementation of most recommendations to reduce waste. Further, any data on cost savings methods may only be for one population set and cannot be extrapolated to the entire LTCF, DOC or DMH populations.

As individual agencies and collaborators on the unit-dose/ return for redispensing project, the Task Force has seen from previous work that there is no single solution that can address rising pharmaceutical costs. The Task Force has not rated the recommended methods because of the lack of data quantifying the reduction in waste on which to make such recommendations. Furthermore, the financial benefit, whether waste reduction, cost savings or a combination of methods would depend on the extent of the individual facility's ability to utilize the method(s). Assessment tools must be developed to determine if the recommended methods can reduce waste and not impose unreasonable costs on the health care delivery system.

Time and resource constraints limited the robustness of the DMA and DPH surveys. However the BRP survey (Attachment 2) and the National Pharmaceutical Council, "Pharmaceutical Benefits Under State Medicaid Assistance

[1] Vital and Health Statistics Series 13, Number 152 The National Nursing Home Survey: 1999 Summary, Data From the National Health Care Survey, Table 21

[2] Massachusetts Extended Care Federation, January 31, 2002, letter in response to the Final Drat Report to the Health Care Task Force

[3] Paone RP, Vogenberg FR,et.al. Medicaion Destruction and Waste Measurement and Management in Longterm Care Facilities. *Consult Pharm* 1996; 11:32-40

Programs, Pharmacy Payment and Patient Cost Sharing" chart (Attachment 5) provided excellent information that can be referenced in the future. Stakeholders are expectedly most interested in reimbursement issues and incentive programs. The Task Force was not able to fully address the financial issues, in part because not all the necessary parties participated. In addition, the cost impact of specific recommendations cannot be immediately assessed.

Task Force Recommendations

The recommended methods for improving medication management are described in the paragraphs below. Following the description is the recommendation for implementation of the method. Key questions used in determining whether to recommend a method include: (1) Has this method shown a positive impact on medication waste reduction in other states or patient care settings; (2) Would this method require start-up monies for equipment or staffing; (3) Would this method require a statutory or regulatory change; and (4) Can this method be employed now without negatively impacting the health care delivery system?

It is important to note that recommended methods adopted by facilities must maintain or improve patient care. The Task Force will continue working with providers to address quality of care issues.

Use of Medical Practice Guidelines

Evidence-based medicine guidelines, (e.g., from the Cochrane Library or National Guideline Clearinghouse, Attachment 14), approved compendial standards and disease state review articles in peer-reviewed literature are available to prescribers and pharmacists. These guidelines or standards can be used by prescribers and pharmacists to assess current drug treatment for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic drug products or less expensive first line drug therapies, therapeutic duplication, drug-disease contraindications and drug-drug interactions in order to improve the quality of care and to conserve program funds or individual expenditures.

This method may require staff time to choose the most beneficial guideline for the patient population and for the clear communication of how the guideline will be used in the facility. No statutory or regulatory changes are required. Prescribers and pharmacists using guidelines and sound therapeutic judgment can treat patients without negatively impacting the health care delivery system.

Currently MassHealth reviews patient records to identify individuals who receive multiple medications. In cases of overutilization of medications, letters of inquiry are sent to prescribers.

Recommendation: The Task Force recommends that prescribers and pharmacists refer to standards and guidelines from evidence based medicine to limit medication mismanagement and waste that can result from sub-optimal, inappropriate or duplicative drug therapy.

Regulatory/Statutory Changes Required: None

Status: Being done now on a limited basis by DMA in polypharmacy utilization reviews.

Requires Involvement of Agencies Outside of Task Force: No

Prescription Ordering and Delivery

When DMA promulgated its regulations on the return for redispensing of unused medications it also published best practice guidelines for LTCFs and LTCF provider pharmacies. Some of the best practices for medication ordering are noted below with suggestions for their implementation.

Prescriptions for drug products that are new therapies for a patient should be ordered in limited quantities. The supply should be just sufficient in quantity to allow an adequate trial period for assessment of patient response. If the therapy is beneficial, then the prescription can be reordered for a larger quantity. The prescription can be

modified if there are dose related problems or side effects. Finally, the medication can be discontinued if the therapy is not successful or not tolerated. Limiting the quantities of first time drug therapies, or issuing starter doses, can decrease prescription drug waste if the therapy is discontinued shortly after it is initiated.

Prescription refill orders can be optimized to prevent dispensing too early or ordering too late. Dispensing too early can cause accumulation of medications that may be discontinued due to change in therapy, discharge or death. Ordering too late may mean that a patient's medications must be delivered separately from the routine delivery incurring extra costs. It has also been suggested that refills of maintenance medications for chronic conditions be ordered in staggered cycles. This method can decrease the possibility of wasting large quantities of medications that were ordered shortly before discharge or death.

The Task Force agrees with DMA's best practices. Professional associations may choose to compile information and experience with new methods of prescription ordering, refilling or delivery systems as implemented by LTCFs and pharmacies. Methods could then be reviewed for ease of implementation, any effect on staff workload, safety and cost savings by other facilities.

Recommendation: The Task Force recommends that prescribers, facilities and pharmacies re-examine current prescripition ordering, refilling and delivery systems to develop reasonable and cost-effective improvements.

Regulatory/Statutory Changes Required: None

Status: Being done now on a limited basis for different patient populations. DMA believes compliance with their best practices is high in LTCFs.

Requires Involvement of Agencies Outside of Task Force: No

Academic or Counter Detailing

Pharmaceutical companies employ salespeople to market drug products by calling upon prescribers and discussing their benefits, improvements or uniqueness of the product. One term for this activity is "product detailing". Government agencies and non-government providers responsible for managing prescription drug benefits are now performing a similar activity, with a different goal, called "academic" or "counter" detailing. These agencies and providers employ clinical pharmacists who provide educational outreach to increase cost effective prescribing. One well-known current topic of academic detailing is the effort to decrease inappropriate or overprescribing of antibiotics.

Last year the Department of Corrections reported a cost savings (avoidance) of $350,000 through the interventions of a clinical pharmacist at SOPS. The projected cost savings this year is expected to be $500,000. The cost of new therapies is increasing sharply at the same time pressure is escalating to control health care costs. A small but important body of research and practice has begun to emerge based on the concept of academic detailing that may present a rational response to these pressures.[4] West Virginia has begun using academic detailing for the Public Employees Insurance Program. DMA has recently hired a clinical pharmacist to begin a program of academic detailing. LTCFs and provider pharmacies could do the same.

Start-up costs can include time for research, development of materials for presentations to prescribers and the actual visits to facilities and prescribers. Each agency in the Task Force works with the local colleges of pharmacy in maintaining intern programs for Pharm.D. candidates. Academic detailing could be an area for agency collaboration with the colleges.

Recommendation: The Task Force recommends that agencies and providers use academic detailing to increase cost effective prescribing.

Regulatory/Statutory Changes Required: None

Status: Being done now in DOC and DMA is beginning a program.

Requires Involvement of Agencies Outside of Task Force: No

[4] Soumerai SB, Avorn J, Principles of Educational Outreach ('Academic Detailing') to Improve Clinical Decisiojn Making. *JAMA* January 26, 1990 Vol 263, No.4 549-556

Collaborative Practice

Collaborative drug therapy management (collaborative practice) is a key component of today's patient care. Collaborative practice is pharmaceutical care provided by a qualified pharmacist who has a written agreement with a physician and requires protocols that are developed and agreed upon by the pharmacist and physician. Activities determined by the protocol can include but are not limited to: initiating, modifying and monitoring a patient's drug therapy; ordering or performing laboratory and related tests, assessing patient response to therapy; and administering medications.

The pharmacist's involvement in developing and maintaining protocols is advantageous in drug product selection, assessment of side effects (for example a trial of a lower dose of an antihypertensive rather than adding a medication for dizziness, a possible side-effect of the antihypertensive), monitoring laboratory and other tests and continual review of new products approved by the Federal Food and Drug Administration (generic or brand-name). It has been shown that when pharmacists are involved in the patient's drug therapy in selected settings there can be a decrease the number of adverse drug events[5]. Costs related to adverse drug events depend on the intervention required which can range from hospital admittance to discontinuing the causative medication.

Collaborative practice for drug therapy management is utilized by the Veteran's Administration and in 38 states. Legislative and/or regulatory actions would be required to fully integrate the pharmacist's expertise into drug therapy management in collaborative practice.

Recommendation: The Task Force recommends pharmacist collaborative practice as a method to improve medication management and decrease medication waste.

Regulatory/Statutory Changes Required: Two bills have been filed, S. 630 and S. 573.

Status: Not allowed at present.

Requires Involvement of Agencies Outside of Task Force: Yes, Board of Registration in Medicine

Formularies/Drug Lists

Formularies are lists that direct drug product choices to those products that are determined to be the most beneficial for a group of patients. Formularies are developed by committees, usually known as Pharmacy and Therapeutics (P and T) Committees. In selecting a drug product for inclusion on a formulary, members of the P and T committee, or equivalent, (pharmacists, prescribers, medical directors and others) review journal articles, clinical experience within the healthcare setting, and other sources of data. The P and T committee provides continual review and oversight of the formulary. Cost and availability can be factors governing choice when two or more drug products are considered to be equivalent with respect to effectiveness and side effects. Formularies may also establish guidelines or policies for the use of a particular drug product or therapeutic class of drugs.

Hospitals and managed care organizations utilize formularies. Limiting the drug products to well-chosen agents can be cost efficient and provides standardization of therapy. The Department of Veteran's Affairs, Veteran's Health Administration manages a national drug formulary. In Massachusetts the State Office of Pharmacy Services uses a formulary approved by the state P and T committee. This formulary is the basis for agency (DOC, DMH, DMR) specific formularies and facility (hospitals, clinics) specific formularies within the agency. The Medicaid programs in some states are involved in or are examining the use of formularies or preferred drugs lists.[6]

The aforementioned facilities and organizations are closed systems. However, LTCFs and the provider pharmacies are open systems and in an open system more careful consideration must be given to the operational aspects of formularies for drug product selection. For MassHealth patients in LTCFs, the LTCF must use the MassHealth Drug List. Nursing facilities use the formulary of the insurer that insures the patient, MassHealth being the payor of last resort.

[5] Leapp LL, Cullen DJ, Clapp MD, et.al. Pharmacist Participation on Physician Rounds and Adverse Drug Events in the Intensive Care Unit *JAMA* 1999;282:267-270.

[6] Kaiser Commission on Medicaid and the Uninsured, States Strive to Limit Medicaid Expenditures for Prescribed Drugs, February 2002

MassHealth has chosen not to develop a formulary, *per se*, which would impose certain requirements on the Medicaid program. The DMA created the MassHealth Drug List (MHDL) to communicate many of the pharmacy requirements of the Medicaid program. While not a formulary, the MHDL has features in common with formularies or preferred drug lists. However, there is more latitude that permits the use of additional drug utilization management techniques that help DMA fulfill it's mission to provide clinically appropriate and fiscally sound drug therapy. Since most of the patients in LTCFs are on Medicaid, the MHDL is the prevailing pharmacy management tool in that setting.

In addition, a study on the pharmacoeconomic impact of implementation of a formulary in the residential and correctional facilities on patient outcomes should be performed. Additional studies are needed of the impact of the MHDL on LTCFs. These studies could be used to determine if the use of a formulary or drug list could result in costs to other areas of health care delivery.

Recommendation: The Task Force recommends consideration of the use of formularies or an equivalent management tool, where safe and appropriate as determined by facility staff, provider pharmacy staff, consultant pharmacists and prescribers.

Regulatory/Statutory Changes Required: None

Status: Formulary used by the State Office of Pharmacy Services; DMA uses MHDL.

Requires Involvement of Agencies Outside of Task Force: No

Therapeutic Interchange

Within a single therapeutic class there may be multiple drugs that are chemically similar and produce similar therapeutic results. An example of a therapeutic class is the "statins", blood lipid lowering agents. Some drugs in this class are lovastatin, simvastatin and pravastatin. Therapeutic interchange would mean, for example, that lovastatin is dispensed when pravastatin was ordered. The concept of therapeutic interchange is not new. Health care facilities utilize therapeutic interchange to prevent duplication of cost and inventory as newly approved drugs expand the choices in a therapeutic class. Drugs chosen must not only produce similar beneficial results but possess equivalent (or better) safety and side-effect profiles. Therapeutic interchange would occur after facility staff, provider pharmacy staff, or consultant pharmacists and prescribers had determined the conditions governing the interchange. While sufficient authority exists to implement therapeutic interchange for Schedule VI drug products, clarification of federal regulations would be necessary regarding limitations on the drug products in federal Schedules II - VI.

Recommendation: The Task Force recommends consideration of therapeutic interchange that is determined appropriate by facility staff, provider pharmacy staff, or consultant pharmacists and prescribers.

Regulatory/Statutory Changes Required: None.

Status: Some application in restricted settings, e.g. hospitals or third parties.

Requires Involvement of Agencies Outside of Task Force: Yes, U.S. Drug Enforcement Administration for drug products in Schedules II - V.

Prior Authorization

Prior authorization is a request from either a prescriber or a provider to the payer for approval to dispense and bill for a prescribed medication. The reasons medications may require prior authorization include but are not limited to known risks for serious side effects, limited success rates, or determination of medical necessity. Prior authorization allows the agency to review an individual's drug therapy to weigh benefits vs. risk or cost.

Identification of drug products requiring prior authorization may be through inclusion in a formulary. DMA uses prior authorization as a method to manage the pharmacy benefit and reduce drug costs in lieu of a formulary. The drug products are listed in the DMA MassHealth Drug List. The Task Force recognizes the potential of a program of prior authorization to reduce medication waste. Start-up costs for an expanded program could include training and software changes in billing programs among others.

Recommendation: The Task Force recommends continued use of prior authorization.

Regulatory/Statutory Changes Required: None

Status: Being done now by DMA.

Requires Involvement of Agencies Outside of Task Force: No

Automated Pharmacy Systems

Automated pharmacy systems (APS) vary depending on the facility and the population served. Automated processes can include, medication order entry into a computer, packaging of unit-dose medications and dispensing a unit-dose packaged medication from a storage cabinet or machine. There are many types of storage units and computer software programs to control and record storage and dispensing of medication. This recommendation covers medication in unit dose dosage forms stocked in decentralized systems that are outside of the pharmacy, i.e., in a LTCF. Prescribers, pharmacists and other medical staff determine the specific medications and quantities that are kept in the machines. The patient's medications are accessed and administered by a nurse in accordance with a medication or prescription order. Frequently, initial access to medications is controlled by a pharmacist offsite who reviews and approves the orders.

Medication waste is reduced because the medications are "dispensed" from the cabinet at the time of administration rather than from a patient specific multi-dose medication card. In a survey by the BRP, nine states out of twenty-eight reported that they allow automated dispensing machines in LTCFs. Experience in hospitals in Massachusetts and LTCFs in other states has shown that APSs can reduce medication waste. However, the cost for computer software, the dispensing unit, conversion to new drug product packaging, training and new pharmacy technician duties should be documented and evaluated prior to recommending the use of APSs.

Recommendation: The Task Force recommends the planning of a demonstration project of the effect of automated dispensing machines on reducing medication waste.

Regulatory/Statutory Changes Required: None

Status: Not being done now.

Requires Involvement of Agencies Outside of Task Force: U.S. Drug Enforcement Administration

Return for Redispensing

Rather than being wasted by disposal, certain unused unit-dose packaged and other unused Schedule VI and over-the-counter medications are returned to the dispensing pharmacy for the purpose of redispensing to patients or residents.

Recommendation: The Task Force recommends the continuation of the return for redispensing of certain unused medications.

Regulatory/Statutory Changes Required: None

Status: Being done now.

Requires Involvement of Agencies Outside of Task Force: None

Release Medications to Patient upon Discharge

Current DPH regulations permit medications to be released to patients or residents on discharge upon the written authorization of a physician, physician assistant or nurse practitioner. DOC has a policy in place that allows inmates to take medications with them upon discharge. DMA requests that when appropriate, medications are released with the patient on discharge.

Recommendation: The Task Force recommends that medications be released with patients upon discharge when determined safe and appropriate and when authorized by a physician, physician assistant or nurse practitioner who are authorized to prescribe.

Regulatory/Statutory Changes Required: None

Status: Being done now.

Requires Involvement of Agencies Outside of Task Force: None

Demonstration Projects

One charge of Chapter 282 was to make recommendations that did not negatively affect other areas of the health care delivery system. However a valid and credible analysis of the risks, costs and benefits of the implementation of any method is beyond the scope of this taskforce. Therefore, demonstration projects would be needed to answer this charge and to ensure that cost savings measures do not come at the expense of patient safety or therapeutic effectiveness.

One recommendation made by the group is to plan for demonstration projects of any methods adopted if they are not already in place. Demonstration projects would be the starting point for data collection. Demonstration projects may also be able to capture data that correlates to any impacts on other patient care activities such as medication administration.

SUMMARY

The Task Force sought information from the literature, other states, local experts, stakeholders and the mandated parties in Chapter 282 (b). From surveys and the literature it was learned what actions other states are taking to control spending on pharmaceuticals. A conference was held on October 28, 2002, and the Task Force used the suggestions put forth by the participants to develop an initial list of recommendations. The final list of recommended methods was determined using the following criteria; (1) Has this method shown a positive impact on medication waste reduction in other states or patient care settings; (2) Would this method require start-up monies for equipment or staffing; (3) Would this method require a statutory or regulatory change; and (4) Can this method be employed now without negatively impacting the medication delivery system. The recommended methods are: use of medical practice guidelines; optimization of prescription ordering; academic detailing; collaborative practice; use of formularies; therapeutic interchange; use of prior authorization; implementation of automated pharmacy systems; return for redispensing; and release of medication with patient upon discharge. Rigorous demonstration projects should be conducted to show the impact of the recommended methods on costs, patient care and the health care delivery system.

The Task Force finds that maximizing clinical effectiveness and operational efficiency, by following in part, in whole, or in combination the recommendations, will improve drug therapy patient outcomes and decrease medication waste. Although no regulatory or statutory changes may be required to implement some of the recommendations, DPH, BRP and/or DMA will need to work with the health care community on guidelines or policies for safe and effective implementation of methods to reduce medication waste. Furthermore, the three member agencies are interested in intra or interagency work to collect and analyze data that will show how the health care delivery system has been affected, positively or negatively. The Task Force recognizes that some patients of residential or correctional facilities may require more costly drug therapy, individualized monitoring for side-effects or therapeutic effectiveness and reiterate that methods to reduce medication waste should not compromise patient health.

As individual agencies and collaborators, the Task Force has seen here and from previous work that there is no single solution that can address medication waste. In a health care system with limited resources, responsible parties will recognize the ever-closer relationship between how actions on behalf of individual patients affect the health of the community's patients.

ACKNOWLEDGEMENTS

Pharmacy Interns:	Uyen Le, Joanna McNeill, Melissa Salerno, Peter Dolan
Staff:	Terri Costanzo, Bianca Leonardi
Stakeholder Meeting Leaders:	Judith Barr, Sc.D; Stephen Feldman, R.Ph.; Professor Robert Paone, Pharm.D. and Dick Gleason, Ed.D.

ABBREVIATIONS

Department of Public Health	DPH
Board of Registration in Pharmacy	BRP
Division of Medical Assistance	DMA
Department of Mental Health	DMH
Department of Mental Retardation	DMR
Department of Corrections	DOC
State Office for Pharmacy Services	SOPS
Long Term Care Facilities	LTCF

GLOSSARY

Academic Detailing: Educational outreach, often by clinical pharmacists, to target less than optimal prescribing.

Automated Pharmacy Systems: medication dispensing technology systems that perform operations or activities relative to the storage, packaging, dispensing or distribution of medications and that collect, control and maintain all transaction information.

May be referred to as “automation,” or APS

Collaborative Practice: A written agreement between a physician and a pharmacist to provide pharmaceutical care services within defined limits.

Formulary: A list that limits the drug product choices available to treat specific patient populations.

MassHealth: State provided health care for certain low- and medium- income people living in Massachusetts.

Prior Authorization: Approval for use of a medication before it is dispensed.

Return for Redispensing: The return of unused unit-dose packaged and certain other unused Schedule VI and over-the-counter medications to pharmacies for the purpose of redispensing to patients or residents.

Therapeutic Interchange: The selection and use of one drug product in a therapeutic category when the multiple drug products in that therapeutic category are considered equivalent in terms of efficacy, safety and outcomes.

Unit Dose: Unit-dose packaging means an individual drug product container, usually consisting of foil, molded plastic or laminate with indentations into which a single solid oral dosage form is placed, with any accompanying materials or components including labeling. Each individual container is fully identifiable and protects the integrity of the dosage form.

Attachment 1

Chapter 282 of the Acts of 2002

AN ACT REDUCING MEDICATION WASTE IN CERTAIN LICENSED FACILITIES.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. (a) The department of public health, in conjunction with the board of registration in pharmacy and the division of medical assistance, shall convene a taskforce to review and make recommendations on methods to reduce medication waste in facilities licensed by the departments of public health, mental health and corrections. The taskforce shall recommend such methods, based on its review, that are determined to be effective in reducing waste without imposing unreasonable costs on the health care delivery system. The taskforce's review shall address, but not be limited to, the following areas: (1) current technology, standards and reimbursement mechanisms for dispensing and distributing medications to facilities; (2) other states' requirements for limiting prescription drug waste and any cost savings realized; (3) the commonwealth's standards for the return and re-dispensing of patient-specific schedule VI prescription drugs; and (4) possible incentive mechanisms to prevent the creation of prescription drug waste.

(b) The taskforce shall consist of up to 2 representatives from each of the following offices: the department of public health, the board of registration in pharmacy and the division of medical assistance. The taskforce shall consult with representatives from the board of registration in nursing, the board of registration in medicine, the department of mental health, the department of corrections, and may consult with representatives from the following entities, as the taskforce deems necessary: the Massachusetts Society of Consultant Pharmacists, Massachusetts Extended Care Federation, Massachusetts Society of Health System Pharmacists, Massachusetts Medical Society, Massachusetts Nurses Association, Massachusetts Hospital Association, the Long-Term Care Pharmacy Alliance, the Home and Health Care Association of Massachusetts and other industry representatives and consultants.

SECTION 2. The taskforce shall submit a report to the joint committee on health care and the house and senate committees on ways and means on or before September 30, 2002.

Approved August 14, 2002.

Attachment 2

State Boards of Pharmacy

	Does your state currently allow automated dispensing devices (ADMs) to be used in LTCF?	If yes, what schedules of prescription drugs/devices are allowed to be dispensed by the ADM?	Are certified technicians allowed to stock the ADMs?	Does your state allow pharmacy departments to be located in a LTCF?	Has your board adopted any new innovations in technology, equipment, or services resulting in cost effective reduction of waste in LTCF?	How can I obtain the enabling regulation/policy (online or hardcopy)?	Comments/additional information
Missouri Contact:Kevin Kinkade	yes	C-II to C-VI	yes	yes	no	hardcopy sent	
Arizona Contact:None	yes	varies on track-record of applicant and policy/procedure submitted	yes	yes	no	upon request	ADM approval depends on the submission of policy and procedure
South Dakota Contact:Dennis M. Jones (605)362-2736	yes	C-II to C-V	yes	yes	no	Internet	Must have pharmacy license to allow ADM
Louisiana Contact:Malcolm Broussard (225)925-6481	yes	all schedules no restriction	yes	yes	no	Internet	
Kentucky Contact:Michael A. Mone	yes	all schedules no restriction	yes	yes	no	Internet	No regulation to prohibit the use of ADM
Rhode Island Contact:Catherine Cordy (401)222-2840	yes	C-II to C-VI	yes	yes	no	upon request	
Oklahoma Contact:None	no	n/a	n/a	no	no		
Kansas Contact:Susan Linn	no	n/a	n/a	no	no		

Delaware Contact:Dave Dryden (302)739-4798	yes	C-III to C-V no C-VI in this state	yes	yes	no	Internet	Non-certified technicians can also restock ADM
Utah Contact:None	no	n/a	n/a	no	no		
Hawaii Contact:Lee Ann Teshima (808)586-2694	no	n/a	n/a	yes	no		
Oregon Contact:Gary Schnabel (gary.a.schnabel@state.or.us)	yes	not specified	not specified	yes	no	Internet	There is no distinction between automated and manual system
Tennessee Contact:Kendall Lynch	no	n/a	n/a	yes	no		This topic was reviewed but the company never asked for the approval for ADD
New Hampshire Contact:None	no	n/a	n/a	yes	yes	upon request	medications dispensed may be returned to pharmacies for credit-- Ph 704.07 (b) (9)
Pennsylvania Contact:Melanie Zimmerman (717)783-7196	no *not specifically addressed by the board	n/a	n/a	yes	no	hardcopy sent	The Board would issue the license, but the DPH regulates LTCF and would have to approve as well
Minnesota Contact:none	no	n/a	n/a	yes	no		
Texas Contact:Steve Morse (512)305-8027	yes	C-II to C-VI	yes	yes * limited to community pharmacy	yes	hardcopy sent	Meds may be returned to pharmacies for reuse provided that meds are in sealed tamper evident packaging and are unopened
Idaho Contact:Jan Atkinson (208)334-2356	yes	C-II to C-V	yes	yes	yes	upon request	Allow return/reuse meds under restricted guidelines if facility is licensed by the Board *Assisted Living Facilities can not return meds b/c not licensed by the Board

Connecticut Contact:Michelle Sylvestre (860)713-6065	no	C-III to C-V and legend drugs	yes	yes	no	upon request	ADM is used for emergency stocks only—sec.210.70(1) and sec.210.250(d)
Nevada Contact:Keith Macdonald (847)698-6227	yes *	C-II to C-V	yes	yes	yes	upon request	new concept of ADM is to eliminate waste or return meds in dose packs to dispensing pharmacies for reuse
Nebraska Contact:none	no	n/a	n/a	yes * if facility obtain a pharmacy license	yes	upon request	medications dispensed may be returned to pharmacies for reuse--Sec.562.109
Alabama Contact:Jerry Moore	yes	not specified	yes	yes	no	hardcopy sent	
North Carolina Contact:Steve Hudson (828)465-2324	yes	C-II to C-VI	yes	yes	no	hardcopy sent	ADM is allow in LTCF provided that the site has a pharmacy permit * Non-certified technicians can restock ADM
Georgia Contact:Laura Sturick	no	n/a	n/a	n/a	no		

Created by: Uyen Le, Pharm.D. Candidate

<u>The following is a brief summary of 24 surveyed State Pharmacy Boards:</u>

- **13** states allow ADM in LTCF with specific drug schedules and allow certified technicians to stock ADD.
  → AL, AZ, MO, SD, LA, KY, RI, DE, OR, TX, ID, NC, NV
  → In addition, DE and NC also allow non-certified technicians to stock ADD under the supervision of the licensed pharmacist

- **11** states do not allow ADM in LTCF. → CT, GA, HI, MN, NE, NH, KS, OK, PA, TN, UT

- **1** state does not allow ADM in LTCF, but allow certified technicians to stock ADM in hospital facilities which is used as emergency stocks only.
  → CT

- **19** states allow LTCF to locate pharmacy departments with in the facility
  → AL, AZ, MO, SD, LA, KY, RI, DE, OR, TX, ID, NC, HI, MN, NH, NE, PA, TN without ADM use

- **5** states allow return of medicines, under certain conditions, to the dispensing pharmacies for reuse and/or credit. → ID, NE, NH, NV,

Attachment 3

DPH and DMA SURVEY

Question: What medication management methods (listed) do you employ in long term care facilities, other residential (non-acute care hospitals) facilities or prisons to prevent or decrease medication waste?

Eighteen states responded: AK, CT, IA, ID, IN, KY, MA, MO, MN, ND, NV, PA, SC, UT, VA, WA, WI, WY

FACILITY TYPE

METHODS	LTCF	Other Residential	Prisons
Automated Dispensing Systems	AK, NV(pending), SC, WA	AK, SC, VA, WA	
Pharmacies in LTCFs'	AK, ND, SC, VA		ND
Formularies	IN, KY	IN, KY	IN, ND
Return for Redispensing	CT, ID, IN, KY, IA. MA, MN, MO, ND, SC, UT, VA, WA, WI	KY, ND, SC	
Prior Authorization (PA)	AK, ID, IN, IA, KY, MA, MN, MO, ND, PA, SC, UT, WA, WV, WY	AK, ID, IN, IA, KY, MA, MN, MO, ND, SC, WA, WV, WY	IN, WY
Therapeutic Interchange	AK, ID, MO,	ID, MO, WA	
Academic Detailing	AK, ID, WA	AK, ID, WA	

Total Net Cost Savings Where Reported: Return for Redispensing: CT $360,000; MO$132,954

Prior Authorization: MO (total for sites listed) $32,603,363

WV (for overall PA program) $14,000,000

Attachment 4

DMA SURVEY

What, if any, incentives does your state offer pharmacies and/or facilities for effectively for managing (preventing) medication waste?

State	Pharmacies?	Annual Cost Savings	Facilities?	Annual Cost Savings
Alaska	None	None	None	None
Arkansas	None	None	None	None
Connecticut	$5.00 per Rx paid if savings to the state	$360,000. +/-	None positive; $30,000. Fine for failure to participate	N/A
Idaho	None	None	None	None
Indiana	They can retain the associated dispensing fee for the returned product	N/A	N/A	N/A
Iowa	None	None	None	None
Kentucky	N/A	N/A	N/A	N/A
Massachusetts	N/A	N/A	N/A	N/A
Minnesota	$0.30 for prescriptions dispensed to LTC facilities in unit dose packaging that the pharmacy packages in house.	Unknown	None	
Missouri	None	N/A	None	N/A
Nevada	Increased dispensing fee for u/d	Unknown	None	
North Carolina	No regulations			
North Dakota	Decision is up to the pharmacist/ First $10 need not be credited/ only cost of meds not fee is credited	$36,000.00	keeps patient happy, saves medication/ more money in budget to pay LTCF	
Ohio	None	None	None	None
Oklahoma	None	None	None	None
Pennsylvania	None	None	None	None
South Carolina	70-80% of all Medicaid LTCF beds are reimbursed at $9.00/ patient/day to the pharmacy provider. Savings accrue to the pharmacy provider. ARM program.	N/A	The cost of most OTC (over the counter) items are included in the facilities' per diem rate and all cost saving accrue to the facility.	N/A
South Dakota	None	None	None	None
Texas	None	None	None	None
Utah	None	N/A	None	N/A
Virginia	Add on dispensing fee and package fees per unit dose	Not Known	N/A	Not Known
Washington	None	None	OTC included in per diem rate for SNFs	
West Virginia	None	None	None	None

Attachment 5

From the National Pharmaceutical Council,

"Pharmaceutical Benefits Under State Medicaid Assistance Programs, Pharmacy Payment and Patient Cost Sharing"

State	Reimbursement Formula	Dispensing Fee	Co-payment
Alabama	AWP-10%; WAC+9.2%	$5.40	$0.50 - $3.00
Alaska	AWP-5%	$3.45 to $11.46 for instate pharmacies	$2.00
Arkansas	AWP-14% for brand	$5.51	per CFR $0.50 - $3.00
California	AWP-5%	$4.05	$1.00
Colorado	AWP-11% OR WAC	$4.00	B/$3.00, G/$0.75
Connecticut	AWP-12%	$3.85	None
Delaware	AWP-12.9%	$3.65	None
DC	AWP-10%	$3.75	$1.00
Florida	AWP-13.25%; WAC+7%	$4.23 - $4.73	None
Georgia	AWP-10%	$4.63 + $0.50 for G or P	G/P: $0.50, B/NP: $0.50 - $3.00
Hawaii	AWP-10.5%	$4.67	None
Idaho	AWP-12%, FUL, SMAC Lower of	$4.94 or $5.54 if delivery is 5x per week to LTC	None
Illinois	AWP-11%	B/$4.00, G/$5.10	$1.00
Indiana	AWP-20% for Generic, AWP-13.5% for Brand	$4.90	$0.50 - $3.00
Iowa	AWP-10%	$5.17	$1.00
Kansas	AWP-10%, IV AWP-50%, blood AWP-30%	$4.50	$2.00
Kentucky	AWP-12%	$4.51	$1.00 for those not exempt
Louisiana	AWP-13.5% (AWP-15% for chains)	$5.77	$0.50 - $3.00
Maine	AWP-10%	$3.35 (plus extra fees for compounding)	$0.50 - $3.00
Maryland	Lower of: WAC+10%, direct+10%, AWP-10%	$4.21	$1.00
Massachusetts	WAC + 6 or FULP or MULP or U&C	$3.50	$2.00
Michigan	AWP-13.5%(1-4 stores), AWP-15.1% (5+ stores)	$3.72	$1.00
Minnesota	AWP-9%	$3.65	None
Mississippi	AWP-10%	$4.91	$1.00
Missouri	AWP-10.43%, WAC+10%	$4.09	$0.50 - $2.00, $5.00 for some 1115 pop.
Montana	AWP-15%	$4.70 for in state, $350 for out of state	$1.00 to $5.00 with a monthly cap of $25
Nebraska	AWP-10%	$3.84 - $5.05	$1.00
Nevada	AWP-15%	$4.76	None
New Hampshire	AWP-12%	$2.50	B/$1.00, G/$0.50
New Jersey	AWP-10%, WAC+30%, AAC for injectables	$3.73 - $4.07	None
New Mexico	Lesser of AWP-12.5%, Federal Upper Limit, State Maximum Allowed Cost, Dept of Justice AWP or Usual and Customary	$3.65	None (except CHIP and working disabled) $2.00
State	Reimbursement Formula	Dispensing Fee	Co-payment
New York	AWP-10%	B/$3.50, G/$4.50	B/$2.00, G/$0.50
North Carolina	lowest of: AWP-10%, State MAC, Federal MAC or u/c	$4.00/Brand and $5.00/Generic	$3.00/Brand and $1.00/Generic

North Dakota	AWP-10%	$4.60	$3.00/ Brand None for Generic
Ohio	WAC+9%	$3.70	None
Oklahoma	Lesser of EAC, FUL, or SMAC + $4.15 dispensing fee for Usual & Customary	Max. $4.15	Rx cost up to $29.99 = $1.00 Rx cost $30.00 and over = $2.00
Oregon	AWP-13%	Retail: $3.50, Inst./NF: $3.80	None
Pennsylvania	AWP-10%	$4.00	$1.00 ($2.00 for GA)
Rhode Island	WAC+5%	OP: $3.40, LTC: $2.85	None
South Carolina	AWP-10%	$4.05	$3.00 for those not exempt
South Dakota	AWP-10.5%	$4.75 up to $5.55 for Unit Dose	$2.00
Tennessee			
Texas	Currently lower of AWP-15% or WAC +12% (Proposed change to lower of AWP-16%, WAC +1% or WAC-12% on FUL and State MAC Drugs)	Currently $5.27 (Proposed $6.04 with implementation of changes noted above to reimbursement formula)	Currently none (Proposed $.50 generic $3.00 brand)
Utah	AWP-12%	$3.90 - $4.40 (based on area)	$1.00 Traditional, $2.00 Non-Traditional
Vermont	AWP-11.9%	$4.25	$1.00 - $2.00
Virginia	AWP-10.25%	$4.25	$2.00/Brand $1.00/Generic
Washington	AWP-14%	$4.20 - $5.20 (based on annual # of Rx)	None
West Virginia	EAC=AWP-12%, FUL or usual & customary, which ever is less	$3.90 (plus extra $1.00 for compounding)	$0.50 - $2.00
Wisconsin	AWP-11.25%	$4.88 (to a maximum $40.11)	$1.00, max $5/recip/pharm/mo
Wyoming	AWP-11%	$5.00	$2.00

From the National Pharmaceutical Council, "Pharmaceutical Benefits Under State Medicaid Assistance Programs, Pharmacy Payment and Patient Cost Sharing"

Legend:

G = Generic

P = Preferred

B = Brand

NP = Non preferred

AWP = Average Wholesale Price

FUL = Federal Upper Limit

Attachment 6

Medication Management Task Force October 28, 2002

Conference Invitee and Participant List

Last Name	First Name	Title	Group
Achin-Sullivan	Nancy	Executive Director	MA Board of Registration in Medicine*
Audet	Adele	Assistant Director	MA Dept. Public Health
Barr	Judith	Sc.D.	Northeastern University, Bouve College of Health Sciences
Bonanno	Theresa	Executive Director	MA Board of Registration in Nursing*
Brandt	Lucinda		MA Division of Health Care Finance and Policy
Buyse	MaryLou	M.D.	MAHP
Carrow	Grant	Director	MA Dept. Public Health
Cayer	George	R.Ph.	Long Term Care Pharmacy Alliance*
Chase	Barbara		MassPRO
Cinqueonce	Carmelo	Executive Director	MA Pharmacists Assoc
Cinqueonce	Carmelo	Executive Director	MA Health Systems Pharmacists*
Coughlin	MaryRose	Director of Nurses	MA County Jail Health Administrators Workgroup
Crane	Bob		PhARMA
Daley	Timothy		Sen. Chandler/ Health Care Committee
Dell'Olio	Louis	Director	State Office of Pharmacy Services (DOC and DMH)*
DeLoach	Charlene		Sen. Moore/ Health Care Committee
Donatelli	Bill	R.Ph.	MA Society of Consultant Pharmacists*
Dreyer	Paul	Director	MA Dept. Public Health
Feldman	Stephen	R.Ph.	ICPS Group
Fidyrch	Mariellen	Executive Director	MA Sheriff's Association
Gleason	Richard	Ed.D.	MA Division of Professional Licensure
Greenlaw	Adam	Research Analyst	Joint Committee on Health Care
Griswold	Paula	Executive Director	MA Coalition for the Prevention of Medical Errors
Heffernan	Peter		MA Dept. of Corrections
Herz	Sue		
Hollander	Ron	President	MA Hospital Assoc.*
Jeffrey	Paul	Pharmacy Program Director	MA Division of Medical Assistance
Kelleher	Patricia	Executive Director	MA Home and Healthcare Association
Lapp	Douglas		MA Division of Health Care Finance and Policy
Lindberg	Bette	Executive Director	MA Board of Registration Physicians Assts.
MacIntrye	Tim	R.Ph.	MA Dept. Public Health
Megathlin	Tony	Investigator	MA AG Office Medicaid Fraud Control Unit
Monahan, Jr.	Charles F.	President	Mass College Pharmacy
Mulligan	Mary Ann		MA Organization of Nurse Executives
Nemmers	Stephen	Executive Director	MA Board of Registration of Nursing Home Administrators
O'Reilly	Elaine		MA Assoc.of Physicians Assistants
Paone	Robert	Professor	MA College of Pharmacy
Pinkham	Julie	Executive Director	MA Nurses Assoc.*
Ryder	William	Regulatory Affairs	MA Medical Society*
Sandberg	Michael		
Sevier	Rita	Deputy Director of Clinical Projects	MA Division of Medical Assistance
Soong	Sharon		Division Health Care Finance and Policy
Sudders	Mary Lou	Commissioner	MA Dept. Mental Health
Thornhill	Gisele	M.D.	MA League of Community Health Centers
Wheeler	Claire		MA Extended Care Fed.*
Young	Charles	Executive Director	MA Board of Registration in Pharmacy

Last Name	First Name	Title	Group
		Central Office	MA Dept Mental Retardation
			Home & Health Care Association of MA*

GENERAL LAWS OF MASSACHUSETTS

TITLE XVI.
PUBLIC HEALTH.

CHAPTER 111. PUBLIC HEALTH.

Chapter 111: Section 25I. Unused medication; return by health care facilities.

Section 25I. The commissioner by rules and regulations may provide that either a resident or consultant pharmacist in a health care facility may return to the pharmacy from which it was purchased any unused medication provided that such medication is sealed in unopened, individually packaged units and within the recommended period of shelf life, and provided that such medication is not a schedule I or II controlled substance as defined in chapter ninety-four C. Such rules and regulations shall permit the pharmacy to which such medication is returned to restock and redistribute such medication, and shall be required to reimburse or credit the purchaser for any such returned medication.

Attacment 8

Massachusetts Department of Public Health

Division of Health Care Quality and Drug Control Program

Guidelines for Use of Unit-Dose Packaging for the Management and Administration of Pharmaceuticals in Long Term Care Facilities

In accordance with Department of Public Health (Department) regulations at 105 CMR 150.000 *et seq.* and 105 CMR 700.000 *et seq.,* long term care facilities (facilities) may use unit-dose packaging for management and administration of pharmaceuticals in accordance with the following guidelines.

Definition(s)

Unit-dose packaging means an individual drug product container, usually consisting of foil, molded plastic or laminate with indentations into which a single solid oral dosage form is placed, with any accompanying materials or components including labeling. Each individual container is fully identifiable and protects the integrity of the dosage form.

Guidelines

1. Written policies and procedures must be developed and implemented that describe the procurement, administration, storage, security, disposal and record-keeping necessary to assure accountability throughout the system, prevent medication errors, impede drug diversion and facilitate the recall of prescription drug products.

2. Policies must include the manner in which provisions for alternate deliveries will be made in the event of an emergency situation (such as daily delivery not possible), new admissions to the facility or a patient or resident choosing an alternate pharmacy provider.

3. Policies and procedures must comply with all applicable state and federal laws. The Department does not require a waiver or advance approval for use of unit-dose packaging.

4. The policies and procedures must be approved by the facility's administration, nursing and medical staffs.

5. Appropriate training must be provided to the nursing staff as part of orientation and whenever significant system changes are made.

6. The system must be periodically evaluated as part of the facility's quality assurance/continuous quality improvement program.

Additional Information

This policy only covers utilization of unit dose packaging for medication management and administration. There are separate requirements for the implementation of a system of return for redispensing of unit-dose medications.

There are additional requirements that apply to the use of automated dispensing machines in long term care facilities[1].

1 Department of Public Health, Circular Letter DHCQ 3-98-380.

Attachment 9

Massachusetts Department of Public Health

Division of Health Care Quality
and
Drug Control Program

Policy on Return for Redispensing of Medications from Long Term Care Facilities

Background

In accordance with M.G.L. c. 111, §25I, the Department of Public Health (Department), permits long term care facilities (LTCFs) licensed by the Department to return unused unit-dose packaged[1] and certain other unused Schedule VI[2] and over-the-counter medications to pharmacies for the purpose of redispensing to patients or residents. Department policy also permits LTCFs to utilize a unit-dose packaging for management and administration of pharmaceuticals to patients or residents.[3]

The Department, working with the Board of Registration in Pharmacy[4], has determined that the return for redispensing of unit-dose packaged medications can be a safe and effective method of pharmaceutical distribution. The return for redispensing of unit-dose packaged medications may contribute to the reduction of medication waste.[5]

Department regulations and this policy govern only the return for redispensing of medications from LTCFs to pharmacies. Regulations of the Board of Registration in Pharmacy govern the receipt and redispensing of such returned medications.

1 Unit-dose packaging means an individual drug product container, usually consisting of foil, molded plastic or laminate with indentations into which a single solid oral dosage form is placed, with any accompanying materials or components including labeling. Each individual container is fully identifiable and protects the integrity of the dosage form. Labeling is in accordance with United States Pharmacopoeia standards compendia and federal and state law. For purposes of this policy traditional "bingo cards" or"bubble packs" are considered an assemblage of multiple, unlabeled, single doses and are not considered to be unit-dose packaging.

2 Schedule VI medications refers to all prescription medications that are not in federal Schedules II - V.

3 Department of Public Health *Guidelines for Use of Unit-Dose Packaging for the Management and Administration of Pharmaceuticals in Long Term Care Facilities.*

4 Board of Registration in Pharmacy, 239 Causeway St., Boston 02114.

5 Department of Public Health Report, May 31, 1996, *Special Project: Dispensing of Unit Dose Medications in LTCFs.*

Requirements

1) The LTCF must have a written policy regarding the return for redispensing of Schedule VI and over-the-counter medications. The policy must address patient or resident safety issues including but not limited to:

   A) ensuring the integrity of drugs subjected to extended and repeated handling, storage and transportation;
   B) ensuring dispensers, repackagers and ultimate users can be identified and notified in the event of a recall;
   C) minimizing opportunities for tampering and diversion; and
   D) ensuring that all medications are stored in accordance with the standards of the United States Pharmacopoeia (USP);

2) Drug products that may be returned are limited to:

A) intact, solid oral dosage forms, in unit-dose packaging and packaged as follows:
i) by the original manufacturer; or
ii) by the pharmacy in accordance with industry standards;
B) ampules;
C) suppositories;
D) parenteral medications in single-dose sealed containers; and
E) medications in multi-dose sealed containers[6], that are dispensed pursuant to an order for an individual patient or resident and from which no doses have been withdrawn;

3) The following must be indicated clearly on each individual unit:

A) if a single active ingredient, the established name of the drug and the quantity of the active ingredient per dosage unit;
B) if a combination drug, the established name and quantity of each active ingredient per dosage unit;
C) lot or control number;
D) expiration or beyond use date;
E) NDC number or equivalent information; and
F) any special storage and handling instructions required by USP standards or state or federal law;

4) The following drug products may not be returned to a pharmacy for redispensing:

A) compounded or reconstituted drugs;
B) drugs that require refrigeration;
C) drugs that are adulterated or misbranded;
D) drugs which have had their integrity, packaging or labeling compromised (e.g., through environmental damage such as water damage, crushing, a broken seal, a torn or marked label); and
E) drugs designated as Schedule II - V controlled substances in accordance with M.G.L. c. 94C, §3.

5) Medications must be returned to the pharmacy (including location) from which they were originally dispensed;

6) Drug products must be returned within 30 days of discontinuation of use by a patient or resident;

7) Drug products must be returned no less than 90 days prior to the beyond use date or expiration date, whichever is earlier;

8) The LTCF must establish tracking and recordkeeping systems for returned medications:

A) Records must include:
i) the date returned to the pharmacy;
ii) prescription number under which the unused medication was originally dispensed;
iii) identity and strength of drug product;
B) This information must be made available to the Department upon request; and
C) These records shall be kept on file for a period of two years; and

9) In accordance with M.G.L. c. 111, §25I, the pharmacy to which such medication is returned shall reimburse or credit the purchaser for any such returned medication.

Attachment 10

POLICY Number PH - 2002 - 01
Policy on Return for Redispensing of Medications from Long Term Care Facilities
Interpretation of M.G.L. c. 94C, § 18(d)
re: Issuance of Prescription by Practitioner or Physician

According to Board of Registration in Pharmacy (Board) regulations (247 CMR); specifically,
9.01: **Code of Professional Conduct for Registered Pharmacists, Pharmacies and Pharmacy Departments**

(1) A registered pharmacist shall at all times conduct professional activities in conformity with federal, state and municipal laws, ordinances and/or regulations, including the regulations of the Board.
(2) A pharmacist shall not dispense drugs, devices, or other substances in a manner which is intended, either directly or indirectly, to circumvent the law.
(3) A pharmacist shall observe the standards of the current United States Pharmacopoeia (USP).
(4) Unless otherwise permitted by law, a pharmacist shall not redispense any medication which has been previously dispensed.

In accordance with the authority granted by M.G.L. c. 111, s. 25I, the Department of Public Health (DPH) has adopted a **Policy on Return for Redispensing of Medications from Long Term Care Facilities** permitting long term care facilities (LTCFs) licensed by DPH to return certain unused unit-dose packaged and certain other unused Schedule VI and over-the-counter medications to pharmacies for the purpose of redispensing to patients. This DPH policy permits LTCFs to utilize unit-dose packaging for the management and administration of pharmaceuticals to patients.
In accordance with 247 CMR 9.01(4), the Board has voted to adopt the DPH's **Policy on Return for Redispensing of Medications from Long Term Care Facilities** (attached in PDF) and permit the redispensing of certain medications from LTCFs in accordance with DPH policy requirements; **provided that the pharmacist redispensing any previously dispensed prescription or non-prescription drug product has determined, using proper professional judgment, that the drug meets USP standards compendia for dispensing**.
Additionally, to redispense permitted medications, the pharmacy will be required to have a **written policy** regarding the return for redispensing of Schedule VI and over-the-counter medications returned from LTCFs. The written policy must address patient safety issues including, but not limited to:

1. Ensuring that the drugs returned were originally dispensed by the same pharmacy;
2. Ensuring that a pharmacist is in control of the redispensing process and has verified each order before redispensing;
3. Ensuring dispensers, repackagers and ultimate users can be identified and notified in the event of a recall;
4. Minimizing opportunities for tampering and diversion;
5. Verifying the drugs are not expired and have a minimum of three (3) months/ninety (90) days remaining to the beyond use date or expiration date, whichever is earlier;
6. Requiring that the pharmacist obtain assurances from a responsible person in charge of the drugs that the drugs have been stored in accordance with the manufacturer's recommendations and current United States Pharmacopoeia standards compendia;
7. **Disallowing** the return or redispensing of any temperature sensitive drug or any drug requiring refrigeration;
8. **Disallowing** the return or redispensing of any compounded or reconstituted medication;
9. **Disallowing** the return or redispensing of any medication which appears to be adulterated or misbranded;
10. **Disallowing** the return or reuse of any drug designated as Schedule II-V controlled substances, in accordance with M.G.L. c. 94C, s. 3;

11. **Disallowing** the return or reuse of drugs which may have had their integrity, packaging or labeling compromised (e.g., through environmental damage such as water damage, crushing, a broken seal, a torn or marked label);

12. Requiring the maintenance of a repackaging record, including the name, strength, lot number, quantity, manufacturer and/or distributor information, date of repackaging, number of packages prepared, number of dosage units in each package, signature of person performing the repackaging, signature of the supervising pharmacist, and such other identifying marks as may be added by the pharmacy for recordkeeping purposes;

13. Requiring the maintenance of a packing manifest for each prescription drug returned by the facility to the pharmacy, to be readily retrievable and maintained at the dispensing pharmacy for a minimum of seven years; and,

14. Requiring that a pharmacist has determined, using proper professional judgment, that all such drugs are appropriate for redispensing.

Board Adoption Date: **March 26, 2002**

Attachment 11

Commonwealth of Massachusetts
Executive Office of Health and Human Services

Division of Medical Assistance

600 Washington Street
Boston, MA 02111
www.mass.gov/dma

MASSHEALTH
TRANSMITTAL LETTER NF-43
June 2002

TO: Nursing Facilities Participating in MassHealth

FROM: Wendy E. Warring, Commissioner

RE: *Nursing Facility Manual* (Unit Dose Return for Certain Drugs)

In an effort to reduce pharmaceutical waste in nursing facilities, the Division has developed a unit-dose return requirement of certain drugs for nursing facilities and pharmacies. This letter transmits revisions to the nursing facility regulations. Under these regulations, the nursing facility must return to the dispensing pharmacy certain unused unit-dose-packaged drugs that were dispensed to MassHealth members.

These new requirements apply only to the eight drugs listed in Appendix F of the *Nursing Facility Manual*. The Division may update this appendix to include additional drugs at a later date. Nursing facilities should refer to 130 CMR 456.621 for specific requirements related to returning unit-dose-packaged drugs.

Department of Public Health Guidelines

The Department of Public Health has issued two documents about unit-dose dispensing and return:

- Policy on Return for Redispensing of Medications from Long Term Care Facilities
- Guidelines for Use of Unit-Dose Packaging for the Management and Administration of Pharmaceuticals in Long Term Care Facilities.

Nursing facilities must adhere to these guidelines when returning drugs in unit-dose packaging. A copy of each of these documents is included with this transmittal letter.

Best Practices

The Division, in concert with nursing facility and pharmacy stakeholders, has also prepared "Best Practices" guidelines. These guidelines advise nursing facilities and pharmacies on how to best manage the unit-dose return policy described in the attached regulations. The "Best Practices" guidelines are also included with this mailing for your information.

Questions or Comments

Nursing facilities may e-mail comments or questions about this new policy to medreturn@nt.dma.state.ma.us. All questions submitted through this electronic mailbox will be summarized and presented to the Massachusetts Extended Care Federation Unit-Dose Return and Redispense Policy Workgroup. This workgroup will provide responses and updates to the nursing facility industry through newsletters, the Internet, and existing workgroups. An information sheet about submitting inquiries through this electronic mailbox is also included with this letter.

These regulations are effective July 1, 2002.

Attachment 12

Commonwealth of Massachusetts
Executive Office of Health and Human Services

Division of Medical Assistance

600 Washington Street
Boston, MA 02111
www.mass.gov/dma

MASSHEALTH
TRANSMITTAL LETTER PHM-45
June 2002

TO: Pharmacies Participating in MassHealth

FROM: Wendy E. Warring, Commissioner

RE: *Pharmacy Manual* (Unit Dose Return for Certain Drugs)

In an effort to reduce pharmaceutical waste in nursing facilities, the Division has developed a unit-dose-dispensing and return requirement of certain drugs for pharmacies and nursing facilities. This letter transmits revisions to the pharmacy regulations. Under these regulations, the pharmacy must fill prescriptions for certain drugs in unit-dose packaging when they are dispensed to MassHealth members residing in a skilled nursing facility. The pharmacy must also credit to the Division amounts paid by the Division for certain unused unit-dose-packaged drugs that have been returned by the nursing facility.

These new requirements apply only to the eight drugs listed in Appendix D of the *Pharmacy Manual*. The Division may update this appendix to include additional drugs at a later date. Pharmacies should refer to 130 CMR 406.446 for specific requirements related to the dispensing and crediting of returned unit-dose-packaged drugs.

The Division will pay the pharmacy a unit-dose return fee in accordance with the rate established by the Massachusetts Division of Health Care Finance and Policy (DHCFP), for each returned prescription credited to the Division. This rate will be adopted in early July, and will be effective July 1, 2002. The Division is recommending the amount of the return fee to be $5 per prescription. Providers may check the DHCFP Web site at www.mass.gov/dhcfp in early July to confirm the amount of the adopted fee.

Updated Billing Guides

Under separate cover, pharmacies will receive updated billing guides from ACS, the Division's Pharmacy On-line Processing vendor, that will describe how to credit the amount of the returned drugs to the Division and receive the return fee. Once the returned drugs are credited to the Division, the pharmacy may redispense the drugs in accordance with guidelines established by the Department of Public Health.

Attachment 13

DOC Medication Management

Tablets Returned

Medications for Each Month

(All Strengths Included)

Dollar Total February - October 2002 $179,060.57

Break out:

February	March	April	May	June	July	August	September	October
Lamivudine/ Zidovudine	Lamivudine/ Zidovudine	Abacavir/Lamavudine/ Zodovudine	Abacavir/Lamavudine/ Zodovudine	Citalopram	Citalopram	Citalopram	Bupropion SR	Bupropion SR
Gabapentim Neurontin	Gabapentim Neurontin	Efavirenz	Efavirenz	Gabapentim Neurontin	Gabapentim Neurontin	Gabapentim Neurontin	Citalopram	Citalopram
Nelfinavir	Nelfinavir	Gabapentim Neuronti	Gabapentim Neurontin	Olanzapine Zyprexa	Olanzapine Zyprexa	Olanzapine Zyprexa	Divalproex Depakote ER	Divalproex Depakote ER
Olanzapine Zyprexa	Olanzapine Zyprexa	Lamivudine/ Zidovudine	Lamivudine/ Zidovudine	Paroxetine Paxil	Paroxetine Paxil	Paroxetine Paxil	Gabapentin Neurontin	Gabapentin Neurontin
Paroxetine Paxil	Paroxetine Paxil	Nelfinavir	Nelfinavir	Quetiapine	Quetiapine	Quetiapine	Mirtazapine Remeron	Mirtazapine Remeron
Risperidone Risperdal	Risperidone Risperdal	Olanzapine Zyprexa	Olanzapine Zyprexa	Risperidone Risperdal	Risperidone Risperdal	Risperidone Risperdal	Olanzapine Zyprexa	Olanzapine Zyprexa
Sertraline Zoloft	Sertraline Zoloft	Paroxetine Paxil	Paroxetine Paxil	Sertraline Zoloft	Sertraline Zoloft	Sertraline Zoloft	Paroxetine Paxil	Paroxetine Paxil
Stavudine	Stavudine	Risperidone Risperdal	Risperidone Risperdal	Bupropion SR	Bupropion SR	Bupropion SR	Quetiapine	Quetiapine

February	March	April	May	June	July	August	September	October
		Sertraline Zoloft	Sertraline Zoloft				Risperidone Risperdal	Risperidone Risperdal
		Stavudine	Stavudine				Sertraline Zoloft	Sertraline Zoloft
							Topiramat e	Topiramate
							Venlafaxine	Venlafaxine
$12,839.14	$33,493.74	$21,245.86	$14,999.82	$10,423.40	$21,990.07	$15,545.44	$19,265.80	$29,257.29

Attachment 14

About the National Guideline Clearinghouse™ (NGC)

The National Guideline Clearinghouse™ (NGC) is a comprehensive database of evidence-based clinical practice guidelines and related documents produced by the Agency for Healthcare Research and Quality (AHRQ) (formerly the Agency for Health Care Policy and Research [AHCPR]), in partnership with the American Medical Association (AMA) and the American Association of Health Plans (AAHP).

The NGC mission is to provide physicians, nurses, and other health professionals, health care providers, health plans, integrated delivery systems, purchasers and others an accessible mechanism for obtaining objective, detailed information on clinical practice guidelines and to further their dissemination, implementation and use.

Key components of NGC include:

- Structured abstracts (summaries) about the guideline and its development;
- A utility for comparing attributes of two or more guidelines in a side-by-side comparison;
- Syntheses of guidelines covering similar topics, highlighting areas of similarity and difference;
- Links to full-text guidelines, where available, and/or ordering information for print copies;
- An electronic forum, NGC-L for exchanging information on clinical practice guidelines, their development, implementation and use;
- Annotated bibliographies on guideline development methodology, implementation, and use.

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